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EXAMINER	
KOSAR, AARON J	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/556,134	YURGELUN-TODD ET AL.	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/07; 3/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are pending and have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the

art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The claims are drawn to methods of treating an individual with secretin to provide a therapeutic effect and wherein the individual has an amygdala-associated disorder. In some dependent claims the individual has a disorder species selected from the group consisting of (i) anxiety disorder, (ii) obsessive-compulsive disorder (OCD), (iii) schizophrenia, (iv) "ADHD", (v) depression, (vi) bipolar disorder, (vii) panic disorders, (viii) post-traumatic stress disorder (PTSD), (ix) phobias, (x) generalized anxiety disorder (GAD), (xi) a substance use disorder, and (xii) cyclothymia. In some dependent claims the species consist of species (vi)-(xii), In some dependent claims the method comprises administering secretin (to an individual) and also administering a medication species (administering *per se*).

The specification fails to provide enabling disclosure as of the time of filing for the claimed method for several reasons. First, skilled artisans had not reached consensus as to the scope of "amygdala-associated disorders". Second, determining whether secretin provides any therapeutic effect, including a curing or preventing effect, for the range of individuals, conditions, and desired effects provided by any mode of administering to the individual or administering *per se*, would require undue experimentation. Finally, the specification in view of the art provides no evidence that at the time of the invention, the skilled artisan would have a reasonable expectation of administering secretin to an individual having any disorder having any

association with the amygdala or that an administering would provide any therapeutic effect, cure, or prevention.

Whereas labeled secretin localizes to the amygdala region, an understanding or consensus as to secretin's activity and effects has not been reached. For example, Beck (2004, US 2004/0146495 A1; PTO-892, reference A) teaches that "it has been proposed that secretin and receptors of secretin are present in the brain areas that are thought to be involved in autism" (Beck, ¶ [0020]); however, Beck further teaches that the function of secretin and the etiology of the disorder autism are unknown, by teaching "it seems likely that secretin regulates neurotransmitters and influences the function of a variety of cells, especially in the 'hippocampal' and 'amygdala' brain areas, where seem to be impaired in autism" but that "[t]here is no published information suggesting a direct relationship between autism and secretin" and that "exactly how secretin works in the brain is not yet fully understood" (Beck, ¶ [0020]).

Later, Williams *et al* (2009, *Cochrane Database of Systematic Reviews*, Issue 2, pages 1-50; PTO-892, reference U) corroborates this uncertainty between secretin and a disorder including autism, teaching "secretin is a gastro-intestinal hormone which has been presented as an effective treatment for autism based on anecdotal evidence" wherein "studies found no evidence that single or multiple dose intravenous secretin is effective across a range of outcomes, and concludes that as such it should not currently be recommended or administered as a treatment for autism." (see for example pages 2, ¶ 2-3 and page 21).

Also, evidenced by Lam, *et al* (2008, *International Review of Cytology*, 265, pages 159-190 (Abstract only); PTO-892, reference V) the presence of secretin in pathways was known, but

the effects and functioning of secretin remained unresolved, by teaching secretin "involvement in neural and neuroendocrine pathways, although the neuroactivity and neural regulation of its release are yet to be elucidated" (Lam, abstract).

The effect of secretin and the treating therewith in the genus of all amygdala-associated disorders are also unresolved and unpredictable as evidenced by Herlihy (2005, RepliGen Corporation Press Release, 2/4/2005, 2 pages; PTO-892, reference W) which teaches intravenous administration of secretin to patients in refractory schizophrenia "did not produce a statistically significant improvement of patient symptoms" (Herlihy, page 1) and Herlihy (2009, RepliGen Corporation Press Release, 3/31/2009, 2 pages; PTO-892, reference X) which teaches that in bipolar disorder/manic depression "current therapies are ineffective and result in numerous side effects".

Taken as a whole, the teachings of Beck, Williams, Lam, and Herlihy teach that even years after the invention, skilled artisans have not fully identified or appreciated the conditions or therapeutic effects of secretin or the treating of disorders associated with the amygdala treatable with secretin, and thus the art remains unpredictable.

Furthermore wherein the claims require treating an individual , "treating" is defined by the as-filed specification as including "intent that a cure, stabilization, or amelioration will result", including "preventative treatment" (page 5, ¶2)(herein referred to as "treating/curing/preventing" as distinguished from a non-curative/non-preventative "treating"); however, treating/curing/preventing embraces not just reducing the incidence, degree, or a risk thereof, but the prevention or an absolute restorative, and/or preventative, and/or prophylactic effect. A treating/curing/preventing having a "curing" or "preventing" or "prophylaxis" effect for

the conditions, individual populations, and desired effects is thus clearly beyond the scope of the instantly disclosed/claimed invention. Please note that for treating/curing/preventing, the term "cure", embracing the effect to further prevent, is an absolute definition which means to stop from recurring and/or occurring and, thus, as with the absolute terms "preventing" and "prophylaxis", requires a higher standard for enablement than does a non-curative/non-preventative "therapeutic" or "treat". For example, in the instant case, treating by curing or prevention or prophylaxis of all amygdala-associated disorders beyond the scope of the instant invention, because the prior art teaches that curing/preventing/prophylaxis remain unresolved, including Freedman (2009, US 2009/0088404 A1; reference C) and Tedford (2006, US 2006/0035889 A1; reference D) which teach that curing remains unknown for conditions, for example, obsessive compulsive disorder (OCD), drug addiction (substance abuse), and autism, respectively, by teaching "[t]here is no known cure for OCD, but it can be treated with anti-depressants" (Freedman, ¶ [0127]) and "[p]resently, there is no cure for drug addiction"(Tedford, ¶ [0004]) and Levitt (2007, US 2007/0072233 A1; reference F) which teaches that "prophylaxis"/"prevention" is not known, for example in schizophrenia, by teaching "[s]ince there is no way of determining if an individual is susceptible to schizophrenia, it is currently unknown if these antipsychotic compounds are useful in the prophylactic treatment of schizophrenia" (¶ [0009]).

Whereas the genus of disorders is not enabled for curing or preventing, the claims also remain not enabled for "treating" because while some symptoms of some psychiatric disorders might be treated in some manner to provide some outcome by administering secretin, not all symptoms of all of the many disorders that could be associated in any way with the amygdala are

so treatable. For example, though the claims embrace many symptoms or disorders, which may reasonable include memory loss, tachycardia, or a migraine in the subjects, the specification does not provide guidance or disclosure for treating, of all symptoms in all instances and in all individuals, with secretin.

Furthermore, the genus of disorders and the control of the symptoms thereof are presently remain untreatable by known methodologies, for example, the disorder of autism for which Pardee (2009, US 2009/0104171 A1, reference E) teaches "[t]he molecular cause of autism is unknown, there is no known cure, and although recent efforts to deliver pharmaceuticals have been reported and patented, none have proved effective in ameliorating and overcoming the multiplicity of neurologic and behavioral symptoms endemic to the disease" (Pardee, ¶ [0003]).

Thus one would not be enabled for curing and/or treating the genus of conditions and symptoms and in all instances, as instantly claimed.

The as-filed specification provides limited guidance as to the administration of a secretin composition to individuals; however, the individuals are healthy individuals and guidance is not provided for individuals having a disorder or for non-human subjects. Specifically, the specification provides guidance only for administering a secretin composition or placebo (i.e. saline) to a population of human subjects (specification, table 1, page 13). Subjects having an amygdala-associated disorder were excluded from the embodiments/working examples wherein the specification teaches that the subjects were healthy control subjects (specification, page 12, line 14) in that the subjects had "no history of psychiatric disorder…all subjects had normal or corrected-normal vision. Subjects with a history of head injury, past psychotropic medication use, seizure disorder, substance use or dependence, or neurological disorder were excluded.

Additionally, subjects who expressed reticence about entering the magnet environment or who could not complete the scanning protocol because of claustrophobia were removed from the study" (specification, page 13). The working examples do not provided for - and exclude from the subject population- administering to individuals other than the exemplified subjects and/or a medicament other than secretin or saline/placebo intravenous monotherapies, and the specification does not teach an effect other than fMRI-BOLD imaging of the healthy control subjects, as instantly disclosed. Thus, the working examples do not appear to include a working embodiment of the claimed method.

Considering the state of the art as discussed by Lam, Williams, Herlihy (2005), and Herlihy (2009), an art-recognized consensus as to the effects of secretin in the treatment of amygdala disorders remains unresolved, and considering the high unpredictability with regards to treating a condition from the diverse and complicated genus of conditions/disorders "associated with the amygdala", including but not limited to the disorders of autism, attention-deficit hyperactivity disorder, and schizophrenia, and the lack of guidance provided in the specification with respect to treating any condition or disorder in an individual with an amygdala-associated condition by administering secretin, one of ordinary skill in the art would be burdened with undue experimentation to treat the disorders or identify an individual in need thereof or determine an effective amount of a composition to provide a therapeutic effect to treat an individual with the instantly claimed compositions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite, because the term "disorders associated with the amygdala" in claim 1 is unclear. The term is unclear, because the manner and degree of "association" is not set forth in the claims. Clarification is required.

The phrase "a therapeutically effective amount" in claims 1 and 2 is indefinite, because the function/effect which is to be achieved and the specific values for the amount, are not recited in the claims. Additionally, the claims do not require that the amount be "effective to treat a disorder of the amygdala", just that it be "therapeutically effective" in some way. (see also MPEP 2173.05(c)(III)).

The term "clinical unit" in claim 2 is indefinite, because the term is not supported by a definition of the term in the specification and is not accepted in the art as referring to any particular amount. Clarification is required. The term "per kilogram" and "of bodyweight" in claim 2 are indefinite, because the object(s) described by the terms are unclear if the terms are further descriptive of the individual of claim 1 or of another object measurable in kilograms or bodyweight. Clarification is required.

The term "ADHD" in claim 4 is indefinite because abbreviations may have multiple meanings. It is unclear if Applicant intends to recite "attention-deficit hyperactivity disorder (ADHD)" or another disorder. Clarification is required.

The term administering in claims 6 and 7 are unclear, because claims 6 and 7 do not require the "administering" of claims 6 and 7 to be an administering to the individual of claim 1,

just that the medication be administered in some way. If Applicant intends the administering of claims 6 and 7 to be further limiting of the administering and directed to the individual of claim 1, the claim should so recite. Clarification is required.

The claims are rejected for the reasons above. Because dependent claims 2-7 depend from rejected claim 1, directly or indirectly, and because the dependent claims do not remedy the grounds of rejection of the rejected claim(s), they are also rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

For the purposes of 102(b) the claims have been interpreted to the extent administering "a therapeutically effective amount" as minimally requiring administering "an amount" of secretin to an individual.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by McMichael (2000, US 6,020,314 A; IDS 5/4/2007).

The claims are anticipated by McMichael, because McMichael teaches administering secretin to a patient or subject diagnosed with a neurological disorder, including autism and attention-deficit hyperactivity disorder ("ADD"/ "ADH"; ADHD) (examples 2-4, claims 1-3). The dose of secretin may be administered intravenously (claim 2) and in a unit amount of a daily dosage 10^{-6} to 10^{-4} mg (claim 1). Because the phrase "2 clinical units" is indefinite, any amount

including the amount taught by McMichael, is interpreted as anticipating "2 clinical units". Administration, as instantly claimed, does not necessarily treat the disorder, but merely requires that the individual be treated; however, McMichael teaches both the administering of secretin to a subject and also, administering secretin wherein while receiving the treatment, the subject showed behaviors including decreased irritability, decreased explosiveness, and that the duration of these better behaviors relapsed within 48 hours after the therapy ended (example 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-7 are rejected under 35 U.S.C. 103(a) as being obvious over McMichael (2000, US 6,020,314 A; IDS 5/4/2007) in view of Renshaw (2002, US 2002/0019364 A1; reference B) and Ford, N. (1996, *J. Traumatic Stress*, 9(4), pages 857-863; reference U') and Nishizono (US 4,443,469 A; reference G).

This rejection addresses the embodiments of the claims in which the symptoms of irritability in psychiatric disorders are treated with secretin.

McMichael teaches administering secretin to a patient, including intravenously (claim 2) and in a unit amount of a daily dosage 10^{-6} to 10^{-4} mg (claim 1). The patient/subject includes a subject diagnosed with a neurological disorder, including autism and "ADD/ADH" (attention-deficit disorder/attention-deficit hyperactivity, ADHD) (examples 2-4, claims 1-3). Administration, as instantly claimed, does not necessarily treat the disorder, but merely requires that the individual be treated whereas McMichael teaches both the administering of secretin and subsequent, transient behavioral changes including decreased irritability, decreased explosiveness, and that the duration of these better behaviors (example 4).

McMichael does not explicitly teach treating conditions other than ADHD. McMichael does not teach further administration with other species of medications.

Renshaw teaches that attention-deficit hyperactivity disorder has the clinical symptoms/hallmarks of "inattention, hyperactivity, and impulsivity, which often respond to treatment with stimulants (e.g., methylphenidate, dextroamphetamine, or magnesium pemoline), although non-stimulant drugs such as beta-blockers (e.g., propranolol or nadolol), tricyclic antidepressants (e.g., desipramine), and anti-hypertensives (e.g., clonidine) are also used"(¶ [0008]). Renshaw also teaches compounds which may be used in psychiatric and substance abuse disorders, including attention-deficit hyperactivity disorder, administered as monotherapies or as combinations, including combining with compounds for the treatment of alcohol or opiate abuse or dependency, or other physiological or psychological conditions associated with alcohol or opiate abuse or dependency, unipolar depression and dysthymia, and attention-deficit hyperactivity disorder. Renshaw further teaches that the composition combination may be administered intravenously (¶ [0058]) and

includes the medications of: (I) an antidepressant, (II) anticonvulsant, (III) antianxiety, (IV) antimanic, (V) antipsychotic, (VI) antiobsessional, (VII) sedative-hypnotic, (VIII) stimulant, or (IX) anti-hypertensive medication, including the species of claims 6 and 7 (see columns 5-6, ¶ [0066]).

Ford teaches that post-traumatic stress disorder (PTSD) is characterized by the symptom of irritability and may be associated with other diagnosis including major depression, reactive psychoses, alcohol dependence and other anxiety disorders (page 857, ¶2; page 858, ¶ 2, last sentence; page 860).

Nishizono teaches that schizophrenia is characterized by irritability and excitement (column 2, lines 13-14).

It would have been obvious to have treated another condition other than the condition taught by McMichael, because McMichael, Renshaw, Ford, and Nishizono taken together, teach that a number of psychiatric disorders were known to be characterized by the symptom of irritability. Since McMichael teaches that secretin may improve irritability, the person of ordinary skill in the art would have been motivated to administer secretin to treat irritability symptoms in any patient displaying them, that is, everyone on the list in claims 4 and 5. One would have had a reasonable expectation of success, because success, to meet the extent of the instantly claimed invention merely requires administering the treatment to the individual and in not any particular outcome, though it would be expected that administering secretin would provide an improvement in irritability.

It would have been obvious to have combined the secretin treatment of McMichael with the medications taught by Renshaw, because each teaches that the respective compositions therein are useful for the same purpose of administering to a patient with a condition, including a condition of attention-deficit hyperactivity disorder, and are useful in being administered by the same mode of administration, including intravenously. One would have been motivated to have provided a combination of the medications or compositions including with the various medication species (I)-(IX), because Renshaw teaches that the medications are useful in combinations with other compounds for the treatment of

psychiatric disorders, including attention-deficit hyperactivity disorder (¶ [0064-0066]). One would have been motivated to have provided the secretin to other disorders because whereas McMichael teaches that treating with secretin results in providing the symptomatic result of decreasing irritability, one would thus be motivated to administer secretin to anyone having irritability symptoms with the reasonable expectation that secretin would decrease said irritability. Also, since the claims do not require that the administering of secretin effect the disorder of the individual, it would thus be expected that secretin would have at least a degree of an effect upon any individual. One would have had a reasonable expectation of success in combining the therapies, because success merely requires treating using compounds useful for the same purpose in their known and predictable manner of functioning in treating a condition.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Lora E Barnhart/
Primary Examiner, Art Unit 1651